

**L.N. 129 of 2013****VETERINARY SERVICES ACT  
(CAP. 437)****Animal Health Requirements for Aquaculture Animals and Products thereof, and on the Prevention and Control of Certain Diseases in Aquatic Animals (Amendment No. 2) Rules, 2013**

IN exercise of the powers conferred by article 5 of the Veterinary Services Act, the Minister for Sustainable Development, the Environment and Climate Change has made the following rules:-

Citation.

**1.** The title of these rules is the Animal Health Requirements for Aquaculture Animals and Products thereof, and on the Prevention and Control of Certain Diseases in Aquatic Animals (Amendment No. 2) Rules, 2013 and these rules shall be read and construed as one with the Animal Health Requirements for Aquaculture Animals and Products thereof, and on the Prevention and Control of Certain Diseases in Aquatic Animals Rules, hereinafter referred to as "the principal rules".

S.L. 437.95

Amends rule 1 of the principal rules.

**2.** Sub-rule (2) of rule 1 of the principal rules shall be substituted by the following:

"(2) The scope of these rules is to transpose Council Directive 2006/88/EC on animal health requirements for aquaculture, animals and products thereof, and on the prevention and control of certain diseases in aquatic animals, repealing and replacing Council Directive 93/53/EEC introducing minimum Community measures for the control of certain fish diseases and Council Directive 95/70/EEC on the introduction of minimum European Community measures for the control of certain disease affecting bivalve molluscs."

Amends rule 3 of the principal rules.

**3.** Sub-rule (1) of rule 3 of the principal rules shall be amended as follows:

(a) immediately before the definition "aquaculture" there shall be added the following new definition:

"Cap. 437. "the Act" means the Veterinary Services Act";

(b) immediately after the definition "authorised processing establishment operator", there shall be added the

following new definitions:

" "the Commission" means the European Commission established by the Treaty on the European Union as amended by the Lisbon Treaty of 2009, subject to subsequent amendments;

"the department" means the department of veterinary services in Malta as established by article 2 of the Act;" and

for the words "the competent authority", wherever they occur in the principal rules, there shall be substituted the words "the department";

(c) immediately after the new definition "the department" there shall be added the following new definition:

" "EFTA Member States" means states which are members of the European Free Trade Association;"

(d) immediately after the definition "farming" there shall be added the following new definition:

" "Member State" means a state which is a member of the European Union;"

(e) immediately after the definition "relaying area" there shall be added the following new definition:

" "Standing Committee on the Food Chain and Animal Health" or "the Committee" means a Committee made up of the representatives of Member States named committee members, who assist and consult the Commission by delivering an Opinion regarding safety measures with respect to animal health issues to be then formally adopted by the Commission in accordance with the appropriate procedure. Such committee procedure covers the entire food supply chain, ranging from animal health issues on the farm to the product which arrives to the final consumer, therefore significantly enhancing its ability to target risks to health wherever they arise in the production of food;"

4. In sub-rule (2) of rule 7 of the principal rules, for the words "that are laid down in Part B of Schedule III" there shall be substituted the words "set out in Schedule III".

Amends rule 7  
of the principal  
rules.

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Amends rule 10  
of the principal  
rules.

**5.** Rule 10 of the principal rules shall be amended as follows:

(a) in sub-rule (3) thereof, for the words "listed in Part B of Schedule III" there shall be substituted the words "set out in Schedule III"; and

(b) in sub-rule (4) thereof, for the words "to be drawn up by the Commission" there shall be substituted the words "set out by the Commission".

Amends rule 12  
of the principal  
rules.

**6.** In sub-rule (2) of rule 12 of the principal rules the words "as referred to in Part A of Schedule III" shall be deleted.

Amends rule 15  
of the principal  
rules.

**7.** In sub-rule (4)(b) of rule 15 of the principal rules, for the words "as referred to in Part A of Schedule III" there shall be substituted the words "as referred to in Schedule III".

Amends rule 17  
of the principal  
rules.

**8.** Sub-rule (3) of rule 17 of the principal rules shall be deleted.

Amends rule 23  
of the principal  
rules.

**9.** Rule 23 of the principal rules shall be amended as follows:

(a) sub-rules (2) and (4) thereof shall be deleted;

(b) sub-rule (3) thereof shall be renumbered as sub-rule (2);

(c) sub-rule (5) thereof shall be renumbered as sub-rule (3); and

(d) in sub-rule (3) thereof, as renumbered, immediately after the words "public health purposes", there shall be added the words "and shall be made available to the public".

Amends rule 28  
of the principal  
rules.

**10.** In rule 28 of the principal rules for the words "with a health status of either category I or III as referred to in Part A of Schedule III" there shall be substituted the words "with a health status categorised as being either "disease-free" or "undetermined" (not known to be infected but not subject to a programme for achieving disease-free status)".

Amends rule 29  
of the principal  
rules.

**11.** In sub-rule (1)(b) of rule 29 of the principal rules for the words "with a health status of either category I or III as referred to in Part A of Schedule III" there shall be substituted the words "with a health status categorised as being either "disease-free" or "undetermined" (not known to be infected but not subject to a programme for achieving disease-free status)".

- 12.** Rule 34 of the principal rules shall be amended as follows: Amends rule 34 of the principal rules.
- (a) in sub-rule (1) thereof, for the words "in accordance with Regulation (EC) No. 1774/2002 of the European Parliament and of the Council of 3 October 2002 which lays down health rules concerning animal by-products not intended for human consumption", there shall be substituted the words "in accordance with Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)"; and
- (b) in sub-rule (2) thereof, for the words "in accordance with Regulation (EC) No. 1774/2002" there shall be substituted the words "in accordance with Regulation (EC) No 1069/2009".
- 13.** In rule 39(d) of the principal rules, for the words "in accordance with Regulation (EC) No. 1774/2002" there shall be substituted the words "in accordance with Regulation (EC) No 1069/2009". Amends rule 39 of the principal rules.
- 14.** Rule 44 of the principal rules shall be amended as follows: Amends rule 44 of the principal rules.
- (a) in sub-rule (1) thereof, the words "(category III as referred to in Part A of Schedule III)" shall be deleted; and
- (b) in sub-rule (2) the words "(category V as referred to in Part A of Schedule III)" shall be deleted.
- 15.** Sub-rule (2) of rule 50 of the principal rules shall be substituted by the following: Amends rule 50 of the principal rules.
- "(2) The department shall submit the declaration referred to in sub-rule (1) to the Standing Committee on Food Chain and Animal Health. Such declaration shall be supported by evidence in a form determined in accordance with the procedure referred to in rule 62(2) and shall be accessible by electronic means to the Commission and to other Member States, in accordance with the requirements of rule 59."
- 16.** Sub-rule (2) of rule 51 of the principal rules shall be deleted, and the whole rule shall be renumbered as rule 51. Amends rule 51 of the principal rules.
- 17.** In sub-rule (1) of rule 53 of the principal rules, the words "as laid down in Part A of Schedule III" shall be deleted. Amends rule 53 of the principal rules.

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Substitutes rule  
54 of the  
principal rules.

**18.** Rule 54 of the principal rules shall be substituted by the following new rule:

"General  
obligations.

54. (1) Effective and continuous cooperation based on the free exchange of information relevant to the implementation of these rules shall be established between the department and any of its other bodies or entities involved in regulating aquaculture, aquatic animals, and food and feed of aquaculture origin. Such information shall also, to the extent necessary, be exchanged with the competent authorities of the other Member States.

(2) The department shall have access to adequate laboratory services and state-of-the-art know-how in risk analysis and epidemiology, having a free exchange of any information relevant to the implementation of these rules between the competent authorities of other Member States and their respective designated laboratories."

Substitutes rule  
55 of the  
principal rules.

**19.** Rule 55 of the principal rules shall be substituted by the following new rule:

"Community  
Reference  
Laboratory.

55. (1) The Community Reference Laboratory designated for the aquatic animal diseases relevant to these rules in accordance with the procedure referred to in rule 62(2) shall act and remain the single point of contact for all designated national reference laboratories in Member States and for the Commission.

(2) The Community Reference Laboratory for aquatic animal diseases shall comply with the functions and duties laid down in Part I of Schedule VI."

Substitutes rule  
56 of the  
principal rules.

**20.** Rule 56 of the principal rules shall be substituted by the following new rule:

"National  
Veterinary  
Laboratory.

56. (1) The National Reference Laboratory designated by the department in Malta is the National Veterinary Laboratory referred to in Part II A of Schedule VI and shall comply with the functions and duties laid down in Part II B of Schedule VI.

(2) The National Veterinary Laboratory shall liaise with the relevant Community Reference Laboratory referred to in rule 55.

(3) The National Veterinary Laboratory shall collaborate with any laboratory designated in other Member States in order to ensure an efficient diagnostic service and methods in accordance with the requirements of rule 57.

(4) The National Veterinary Laboratory shall be adequately equipped and staffed with the appropriate numbers of trained personnel to carry out the laboratory investigations required in accordance with these rules."

**21.** Rule 57 of the principal rules shall be substituted by the following new rule:

Substitutes rule  
57 of the  
principal rules.

"Diagnostic  
services and  
methods.

57. The department shall ensure that:

(a) laboratory examinations for the purposes of these rules are carried out in the National Veterinary Laboratory designated for such purpose by the department;

(b) laboratory examinations in the case of suspicion and to confirm the presence of the diseases listed in Part II of Schedule IV are carried out by diagnostic methods established in accordance with the procedure referred to in rule 62(2); and

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(c) the National Veterinary Laboratory designated for diagnostic services in accordance with this rule shall comply with the functions and duties laid down in Part II B of Schedule VI."

Amends rule 58 of the principal rules.

**22.** Rule 58 of the principal rules shall be amended as follows:

(a) in sub-rule (1) thereof, for the words "carrying out their duties, and the Commission shall inform the competent authority of the results of any such inspections and audits." there shall be substituted the words "carrying out their duties."; and

(b) in the proviso to sub-rule (3) thereof, for the words "in accordance with the procedure referred to in rule 62(3)" there shall be substituted the words "in accordance with the procedure referred to in rule 62(2)".

Amends rule 59 of the principal rules.

**23.** Sub-rule (2) of rule 59 of the principal rules shall be deleted, and the whole rule shall be renumbered as rule 59.

Substitutes rule 60 of the principal rules.

**24.** Rule 60 of the principal rules shall be substituted by the following new rule:

"Offences and penalties.

60. The department shall take all necessary administrative measures to ensure conformity with these rules, and shall where applicable apply such penalties prescribed in terms of the Act if any person fails to abide by these rules. Such penalties shall apply without prejudice to any criminal penalties which may be applied in this regard and in pursuance of any infringements committed against the provisions contained in these rules."

Amends rule 62 of the principal rules.

**25.** Rule 62 of the principal rules shall be amended as follows:

(a) sub-rule (2) thereof shall be substituted by the following:

"(2) Where reference is made to this sub-rule, the procedure set out in the definition "Standing Committee on the Food Chain and Animal Health" in rule 3(1) shall apply."; and

(b) sub-rules (3) and (4) thereof shall be deleted.

26. Schedule VI to the principal rules shall be substituted with the following new Schedule:

Substitutes  
Schedule VI to  
the principal  
rules.

"Schedule VI

Functions and duties of Laboratories

PART I

Community Reference Laboratory - Functions and Duties

1. The Community Reference Laboratory shall in accordance with rule 55 fulfil the following requirements. It shall:

- (a) have suitably qualified staff with adequate training in diagnostic and analytical techniques applied in its area of competence, including trained personnel available for emergency situations occurring within the Community;
- (b) possess the equipment and products needed to carry out the tasks assigned to it;
- (c) have an appropriate administrative infrastructure;
- (d) ensure that their staff respect the confidential nature of certain subjects, results or communications;
- (e) have sufficient knowledge of international standards and practices;
- (f) have available, as appropriate, an updated list of available reference substances and reagents and an updated list of manufacturers and suppliers of such substances and reagents;
- (g) take account of research activities at national and Community level.

The Community Reference Laboratory shall remain the contact point for the national reference laboratories in the Member States, and for the Commission.

2. Moreover, the Community Reference Laboratory shall:

- (a) coordinate, in consultation with the Commission, the methods employed in the Member States for diagnosing the disease concerned, specifically by:
  - (i) typing, storing and, where appropriate, supplying strains of the pathogen of the relevant disease to



facilitate the diagnostic service in the Community;

(ii) supplying standard sera and other reference reagents to the national reference laboratories in order to standardise the tests and reagents used in each Member State, where serological tests are required;

(iii) organising periodic comparative tests (ring tests) of diagnostic procedures at Community level with the national reference laboratories designated by the Member States, in order to provide information on the methods of diagnosis used and the results of tests carried out in the Community;

(iv) retaining expertise on the relevant disease pathogen and other pertinent pathogens to enable rapid differential diagnosis;

(b) assist actively in the diagnosis of outbreaks of the relevant disease in Member States by receiving pathogen isolates for confirmatory diagnosis, characterisation and epizootic studies;

(c) facilitate the training or retraining of experts in laboratory diagnosis with a view to harmonising diagnostic techniques throughout the Community;

(d) collaborate, as regards methods of diagnosing animal diseases falling within their areas of competence, with the competent laboratories in third countries where those diseases are prevalent;

(e) collaborate with the relevant OIE reference laboratories with regard to exotic diseases listed in Part II of Schedule IV under their responsibility;

(f) collate and forward information on exotic and endemic diseases, that are potentially emerging in Community aquaculture.

## PART II

### A. National Veterinary Laboratory

The National Reference Laboratory in Malta is the National Veterinary Laboratory referred to in rule 56, situated at Civil Abattoir, Albertown, Marsa.

## B. Functions and duties of the National Veterinary Laboratory

1. The National Veterinary Laboratory designated pursuant to rule 56 shall be responsible for coordinating the diagnostic standards and methods. Moreover, it shall:

(a) undertake to notify, without delay, the department whenever the laboratory is aware of a suspicion of any of the diseases referred to in Schedule IV;

(b) coordinate, in consultation with the relevant Community Reference Laboratory, the methods employed in other Member States for diagnosing the diseases concerned under their responsibility;

(c) assist actively in the diagnosis of outbreaks of the relevant disease by receiving pathogen isolates for confirmatory diagnosis, characterisation and epizootic studies;

(d) facilitate the training or retraining of experts in laboratory diagnosis with a view to harmonising diagnostic techniques in Malta;

(e) ensure confirmation of positive results of all outbreaks of exotic diseases listed in Part II of Schedule IV, and of primary outbreaks of non-exotic diseases listed in that Schedule;

(f) organise periodic comparative tests (ring tests) of diagnostic procedures at national level with the laboratories designated by the Member States in order to provide information on the methods of diagnosis used and the results of tests carried out in the Malta;

(g) cooperate with the Community Reference Laboratory referred to in Article 55 and participate in the comparative tests organised by national reference laboratories in other Member States;

(h) ensure a regular and open dialogue with the department;

(i) operate and be assessed and accredited in accordance with the following European Standards account being taken of the criteria for different testing methods laid down in these rules:

(i) EN ISO/IEC 17025 on 'General requirements

for the competence of testing and calibration laboratories’;

(ii) EN 45002 on ‘General criteria for the assessment of testing laboratories’;

(iii) EN 45003 on ‘Calibration and testing laboratory accreditation system - General requirements for operation and recognition’.

2. The accreditation and assessment of testing laboratories referred to in point 1(i) may relate to individual tests or groups of tests.

3. The National Veterinary Laboratory may not comply with the requirements referred to in point 1(i) (i), where operation under EN ISO/IEC 17025 is practically difficult, provided the laboratory operates under quality assurance in line with the guidelines in ISO 9001.

4. The National Veterinary Laboratory may take advantage of the skills and capacity of other laboratories for one or more of the diseases under their responsibility, provided that these laboratories comply with the relevant requirements of this Part of the Schedule. However, the National Veterinary Laboratory shall remain the contact point for the department in Malta and for the Community reference laboratory."

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